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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### Establishment of Prescription Drug User Fee Rates for Fiscal Year 2000

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates for prescription drug user fees for fiscal year (FY) 2000. The Prescription Drug User Fee Act of 1992 (the PDUFA), as amended by the Food and Drug Administration Modernization Act of 1997 (the FDAMA), authorizes FDA to collect user fees for certain applications for approval of drug and biological products, on establishments where the products are made, and on such products. Fees for applications for FY 2000 were set by the FDAMA, subject to adjustment for inflation. Total application fee revenues fluctuate with the number of fee-paying applications FDA receives. Fees for establishments and products are calculated so that total revenues from each category will approximate FDA's estimate of the revenues to be derived from applications.

**FOR FURTHER INFORMATION CONTACT:** Michael E. Roosevelt, Office of Financial Management (HFA-120), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5088.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The PDUFA (Public Law 102-57 1), as amended by the FDAMA (Public Law 105-1 15), establishes three different kinds of user fees. Fees are assessed on: (1) Certain types of applications and supplements for approval of drug and biologic products, (2) certain establishments where such products are made, and (3) certain products (21 U.S.C. 379h(a)). When **certain** conditions are met, FDA may waive or reduce fees (21 U.S.C. 379h(d)).

For FY 1998 through 2002, under the amendments enacted in the FDAMA, the application fee rates are set in the statute, but are to be adjusted annually for cumulative inflation since FY 1997. Total application fee revenues are structured to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases.

Each year from FY 1998 through 2002, FDA is required to set establishment fees and product fees so that the estimated total fee revenue from each of these two categories will equal the total revenue FDA expects to collect from application fees that year. This procedure continues the arrangement under which one-third of the total user fee revenue is projected to come from each of the three types of fee: Application fees, establishment fees, and product fees.

This notice establishes fee rates for FY 2000 for application, establishment, and product fees. These fees are retroactive to October 1, 1999, and will remain in effect through September 30, 2000. For fees already paid on applications and supplements submitted on or after October 1, 1999, FDA will bill applicants for the difference between fees paid and fees due under the new fee schedule. For applications and supplements submitted after December 31, 1999, the new fee schedule must be used. Invoices for establishment and product fees for FY 2000 will be issued in December 1999, using the new fee schedules.

## **II. Inflation and Workload Adjustment Process**

The PDUFA, as amended by the FDAMA, provides that fee rates for each FY shall be adjusted by notice in **the Federal Register**. The adjustment must reflect the greater of: (1) The total percentage change that occurred during the preceding FY in the Consumer Price Index (CPI) (all items; U.S. city average), or (2) the total percentage pay change for that FY for Federal employees stationed in the Washington, DC metropolitan area. The FDAMA provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)(1)).

The FDAMA also structures the total application fee revenue to increase or decrease each year as the number of fee-paying applications submitted to FDA increases or decreases. This provision allows revenues to rise or fall as this portion of FDA's workload rises or falls. To

implement this provision, each year FDA will estimate the number of fee-paying applications it anticipates receiving. The number of applications estimated will then be multiplied by the inflation-adjusted statutory application fee. This calculation will produce the FDA estimate of total application fee revenues to be received.

The PDUFA also provides that FDA shall adjust the rates for establishment and product fees so that the total revenues from each of these categories is projected to equal the revenues FDA expects to collect from application fees that year. The FDAMA provides that the new fee rates based on these calculations be adjusted within 60 days after the end of each FY (21 U.S.C. 379h(c)(2)).

### **III. Inflation Adjustment and Estimate of Total Application Fee Revenue**

The FDAMA provides that the application fee rates set out in the statute be adjusted each year for cumulative inflation since 1997. It also provides for total application fee revenues to increase or decrease based on increases or decreases in the number of fee-paying applications submitted.

#### ***A. Inflation Adjustment to Application Fees***

Application fees are assessed at different rates for qualifying applications depending on whether the applications require clinical data for safety or effectiveness (other than bioavailability or bioequivalence studies) (21 U.S.C. 379h(a)(1)(A) and 379h(b)). Applications that require clinical data are subject to the full application fee. Applications that do not require clinical data and supplements that require clinical data are assessed one-half the fee of applications that require clinical data. If FDA refuses to file an application or supplement, 75 percent of the application fee is refunded to the applicant (21 U.S.C. 379h(a)(1)(D)).

The application fees described above are set out in the FDAMA for FY 2000 (\$256,338 for applications requiring clinical data, and \$128,169 for applications not requiring clinical data or supplements requiring clinical data) (21 U.S.C. 379h(b)(1)), but must be adjusted for cumulative

inflation since 1997. That adjustment each year is to be the greater of : (1) The total percentage change that occurred during the preceding FY in the CPI, or (2) the total percentage pay change for that FY for Federal employees, as adjusted for any locality-based payment applicable to employees stationed in the District of Columbia. The FDAMA provides for this annual adjustment to be cumulative and compounded annually after 1997 (see 21 U.S.C. 379h(c)).

The adjustment for FY 1998 was 2.45 percent (62 FR 64849, December 9, 1997). This was the greater of the CPI increase for FY 1997 (2.15 percent) or the increase in applicable Federal salaries (2.45 percent).

The adjustment for FY 1999 was 3.68 percent (63 FR 70777 at 70778, December 22, 1998). This was the greater of the CPI increase for FY 1998 (1.49 percent) or the increase in applicable Federal salaries (3.68 percent).

The adjustment for FY 2000 is 4.94 percent. This is the greater of the CPI increase for FY 1999 (2.62 percent) or the increase in applicable Federal salaries (4.94 percent).

Compounding these amounts (1.0245 times 1.0368 times 1.0494) yields a total compounded inflation increase of 11.47 percent for FY 2000. The adjusted application fee rates are computed by adding one to the decimal equivalent of this percent (0.1147) and multiplying this amount (1.1147) by the FY 2000 statutory application fee rates stated above (\$256,338 for applications requiring clinical data, and \$128,169 for applications not requiring clinical data or supplements requiring clinical data). For FY 2000 the adjusted application fee rates are \$285,740 for applications requiring clinical data, and \$142,870 for applications not requiring clinical data or supplements requiring clinical data. These amounts must be submitted with all applications during FY 2000.

#### *B. Estimate of Total Application Fee Revenue*

Total application fee revenues for FY 2000 will be estimated by multiplying the number of fee-paying applications FDA receives in FY 2000 (from October 1, 1999, through September 30, 2000) by the fee rates calculated in the preceding paragraph. Before fees can be set for establishment and product fee categories, each of which are projected to be equal to total revenues

FDA collects from application fees, FDA must first estimate its total FY 2000 application fee revenues. To do this FDA first determines its FY 1999 fee-paying full application equivalents, and uses that number in a linear regression analysis to predict the number of fee-paying full application equivalents expected in FY 2000. This is the same technique applied last year.

In FY 1999, FDA received and filed 119 human drug applications that required clinical data for approval, 17 that did not require clinical data for approval, and 112 supplements to human drug applications that required clinical data for approval. Because applications that do not require clinical data and supplements that require clinical data are assessed only one-half the full fee, the equivalent number of these applications subject to the full fee is determined by summing these categories and dividing by two. This amount is then added to the number of applications that require clinical data to arrive at the equivalent number of applications that may be subject to full application fees.

In addition, as of September 30, 1999, FDA refused to file, or firms withdrew before filing, six applications that required clinical data, three applications that did not require clinical data, and four supplements requiring clinical data. The full applications refused for filing or withdrawn before filing pay one-fourth the full application fee and are counted as one-fourth of an application; the applications that do not require clinical data and the supplements refused for filing or withdrawn before filing pay one-eighth of the full application fee and are each counted as one-eighth of an application.

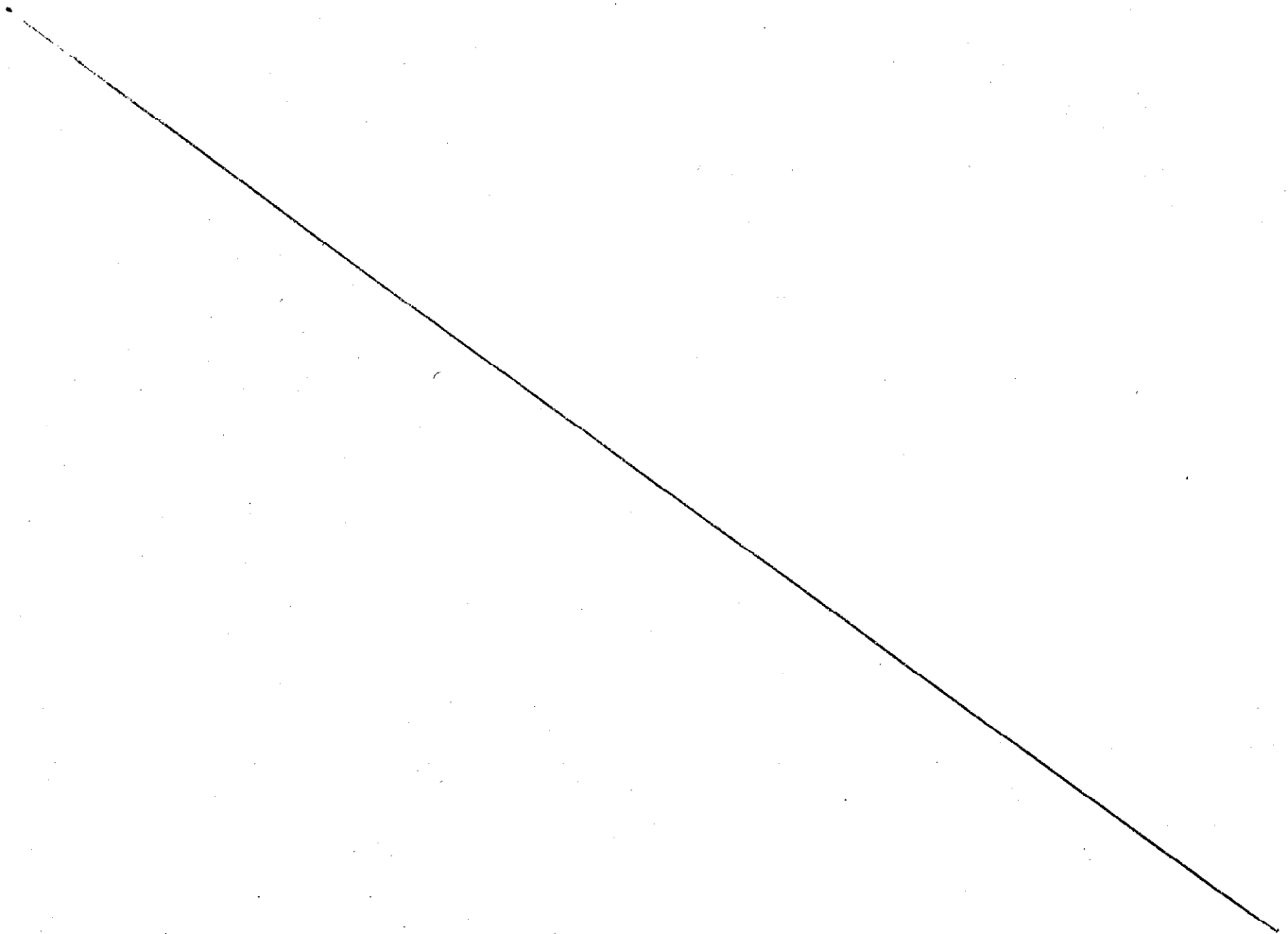
Using this methodology, the number of full application equivalents that were submitted for review in FY 1999 was 186, before any exemptions, waivers or reductions. Under the FDAMA, FDA waives fees for certain small businesses submitting their first application and certain orphan products, and certain supplements for pediatric indications are exempted from application fees. In addition, the FDAMA provides a number of other grounds for waivers (public health necessity, preventing significant barriers to innovation, and fees exceed the cost). In FY 1999, waivers or exemptions were applied to 35 full application equivalents (thirteen for orphan products, seven

for small businesses, five for pediatric supplements, and ten miscellaneous exemptions/waivers). Therefore, for FY 1999, FDA estimates that it received the equivalent of 151 (186 minus 35) full application equivalents that will pay fees, after allowing for exemptions, waivers and reductions.

A linear regression line based on the adjusted number of fee-paying full application equivalent submissions since 1993, and including our FY 1999 total of 151 fee-paying full application equivalents, projects the receipt of 158 fee-paying full application equivalent submissions in FY 2000, as reflected in Table 1 of this document and the graph below.

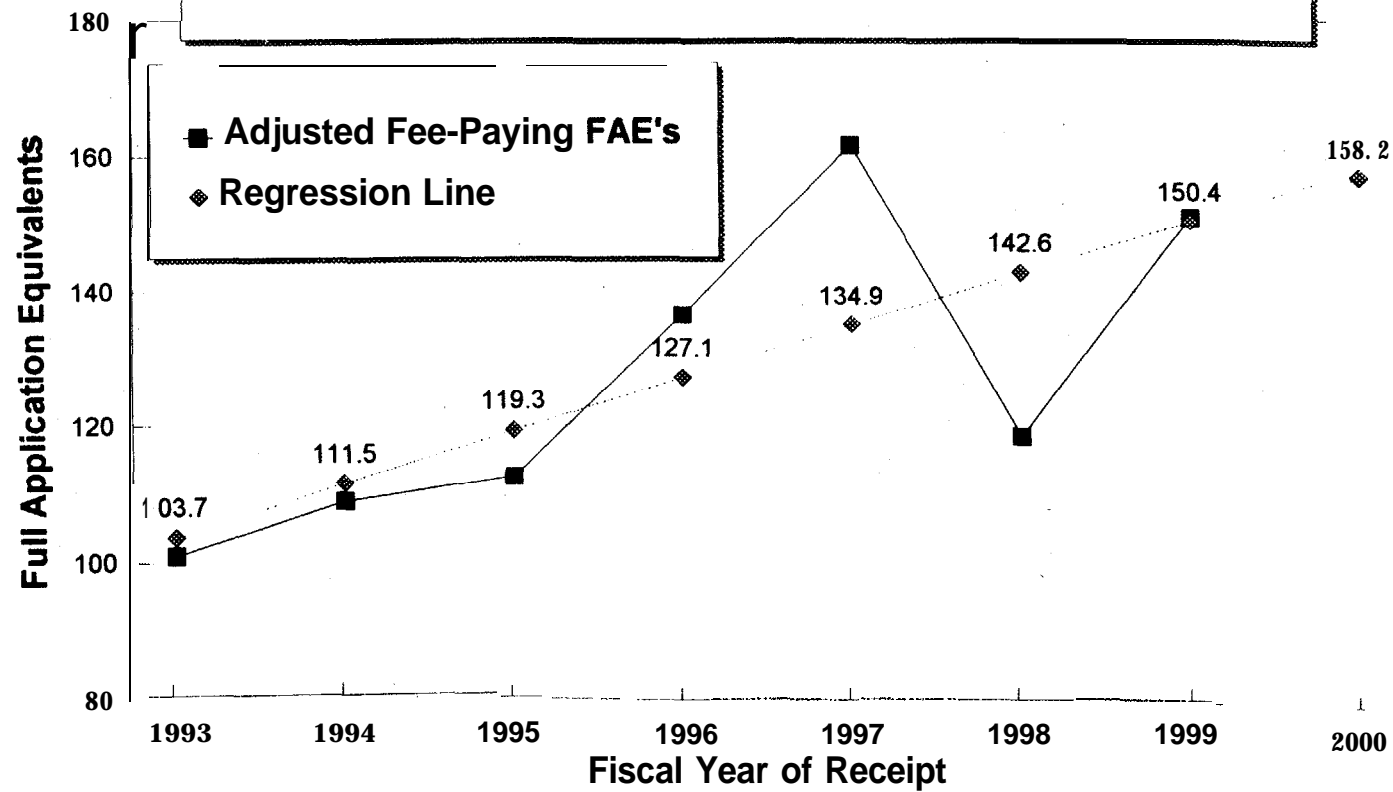
**Table 1.**

Fiscal Year	1993	1994	1995	1996	1997	1998	1999	2000
Adjusted fee-paying FAE's	101.0	108.9	112.5	136.3	161.5	118.5	150.9	
Regression line	103.7	111.5	119.3	127.1	134.9	142.6	150.4	158.2



## Fee-Paying Full Application Equivalents (FAE's)

Using 1993-1999 Data, Adjusted for PDUFA II Rules



The total FY 2000 application fee revenue is estimated by multiplying the adjusted application fee rate (\$285,740) by the equivalent number of applications projected to qualify for fees in FY 2000 (158), for a total estimated application fee revenue in FY 2000 of \$45,146,920. This is the amount of revenue that FDA is also expected to derive both from establishment fees and from product fees.

#### **IV. Fee Calculations for Establishment and Product Fees**

##### *A. Establishment Fees*

At the beginning of FY 1999, the establishment fee was based on an estimate of 318 establishments subject to fees. For FY 1999, 343 establishments qualified for and were billed for establishment fees, before all decisions on requests for waivers or reductions were made. FDA estimates that a total of 25 establishment fee waivers will be granted in FY1999, for a net of 318 fee-paying establishments, and will use this number again for its FY 2000 estimate of establishments paying fees, after taking waivers into account. The fee per establishment is determined by dividing the adjusted total fee revenue to be derived from establishments (\$45,146,920), by the estimated 318 establishments, for an establishment fee rate for FY 2000 of \$141,971 (rounded to the nearest dollar).

##### *B. Product Fees*

At the beginning of FY 1999, the product fee was based on an estimate that 2,224 products would be subject to product fees. By the end of FY 1999, 2,317 products qualified and were billed for product fees before all decisions on requests for waivers or reductions were made. Assuming that there will be about 55 waivers granted, FDA estimates that 2,262 products will qualify for product fees in FY 1999, after allowing for waivers and exemptions, and will use this number for its FY 2000 estimate. Accordingly, the FY 2000 product fee rate is determined by dividing the adjusted total fee revenue to be derived from product fees (\$45,146,920) by the estimated 2,262 products for a product fee rate of \$19,959 (rounded to the nearest dollar).



## V. Adjusted Fee Schedules for FY 2000

The fee rates for FY 2000 are set out in Table 2 of this document:

**Table 2.**

Fee Category	Fee Rates for FY 2000
Applications:	
Requiring clinical data	\$285,740
Not requiring clinical data	\$142,870
Supplements requiring clinical data	\$142,870
Establishments	\$141,971
Products	\$19,959

## VI. Implementation of Adjusted Fee Schedule

### A. Application Fees

Any application or supplement subject to fees under the PDUFA that is submitted after December 31, 1999, must be accompanied by the appropriate application fee established in the new fee schedule. Payment must be made in U.S. currency by check, bank draft, or U.S. postal money order payable to the order of the U.S. Food and Drug Administration. Please include the user fee ID number on your check. Your check can be mailed to: Food and Drug Administration, P.O. Box 360909, Pittsburgh, PA 15251-6909.

If checks are to be sent by a courier that requests a street address, the courier can deliver the checks to: Mellon Bank, Three Mellon Bank Center, 27th Floor (FDA 360909), Pittsburgh, PA 15259-0001. (Note: This Mellon Bank Address is for courier delivery only.) Please make sure that the FDA P.O. Box number (PO Box 360909) is on the enclosed check.

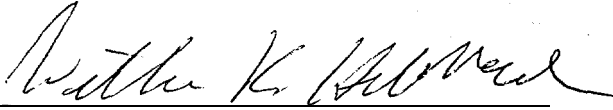
FDA will bill applicants who submitted application fees from October 1 to December 31, 1999, for the difference between the amount they submitted and the amount specified in the Adjusted Fee Schedule for FY 2000.

### B. Establishment and Product Fees

By December 31, 1999, FDA will issue invoices for establishment and product fees for FY 2000 under the new Adjusted Fee Schedule. Payment will be due by January 31, 2000. FDA will

issue invoices in October 2000 for any products and establishments subject to fees for FY 2000 that qualify for fees after the December 1999 billing.

Dated: December 21, 1999  
December 21, 1999

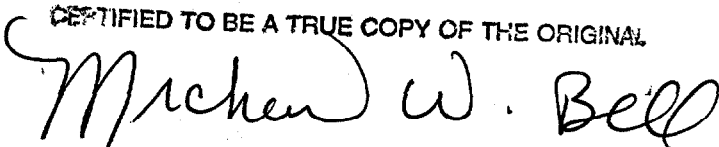


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Policy, Planning, and Legislation

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